Complete Summary

GUIDELINE TITLE

Management of abnormal cervical cytology and histology.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Management of abnormal cervical cytology and histology. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2005 Sep. 20 p. (ACOG practice bulletin; no. 66). [214 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Abnormal uterine cervix cytology, including:

- Atypical squamous cells
- Squamous intraepithelial lesions (cervical intraepithelial neoplasia grades 1-3)
- Atypical glandular cells
- Endocervical adenocarcinoma in situ
- Cervical cancer

GUIDELINE CATEGORY

Management
Screening
Treatment

CLINICAL SPECIALTY

Obstetrics and Gynecology
Pathology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To define strategies for diagnosis and management of abnormal uterine cervical cytology and histology

TARGET POPULATION

Women and adolescent girls with an abnormal uterine cervical epithelial screening test, including pregnant women and adolescents and those who are human immunodeficiency virus (HIV)-positive

INTERVENTIONS AND PRACTICES CONSIDERED

Screening

1. Cytology assessment (Pap smear)
2. Human papillomavirus (HPV) deoxyribonucleic acid (DNA) testing
3. Frequency of cervical cancer screening

Management/Treatment

1. Colposcopy
2. Directed biopsy
3. Endocervical curettage
4. Four-quadrant ectocervical biopsy
5. Loop electrosurgical excision procedure (LEEP)
6. Cold-knife conization
7. Laser therapy
8. Cryotherapy
9. Hysterectomy

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of cervical epithelial testing
- Predictive value of tissue sampling methods on progression to cervical cancer
- Incidence of progression to cervical cancer

- Risk of recurrence

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and April 2005. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

I: Evidence obtained from at least one properly designed randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

The following recommendations are based on good and consistent scientific evidence (Level A):

- Women with atypical squamous cell (ASC) cytology results may undergo immediate colposcopy, triage to colposcopy by high-risk human papillomavirus (HPV) deoxyribonucleic acid (DNA) testing, or repeat cytology screening at 6 and 12 months. Triage to colposcopy should occur after positive HPV test results or ASC or higher-grade diagnosis. Women with ASC who test negative for HPV or whose HPV status is unknown and test negative for abnormalities using colposcopy should have a repeat cytology test in 1 year.
- Most women with ASC who are HPV positive or women with ASC for which high-grade squamous intraepithelial lesion (HSIL) cannot be excluded (ASC-H), low-grade squamous intraepithelial lesion (LSIL), or HSIL test results should undergo colposcopy.
- For women with an ASC HPV-positive test result or ASC-H or LSIL cytology result and a negative initial colposcopy or a histologic result of cervical intraepithelial neoplasia grade 1 (CIN 1), optimal follow-up is repeat cervical cytology tests (not screening) at 6 and 12 months or an HPV test at 12 months; a repeat colposcopy is indicated for a cytology result of ASC or higher-grade abnormality or a positive high-risk HPV test.
- The recommendation for follow-up of untreated CIN 1 includes cytology tests at 6 and 12 months with colposcopy for an ASC or higher-grade result, or a single HPV test at 12 months, with colposcopy if the test result is positive.

The following recommendations are based on limited and inconsistent scientific evidence (Level B):

- Endocervical sampling using a brush or curette may be undertaken as part of the evaluation of ASC and LSIL cytology results and should be considered as part of the evaluation of atypical glandular cells (AGC), adenocarcinoma in situ (AIS), and HSIL cytology results.
    - Endocervical sampling is recommended at the time of an unsatisfactory colposcopy or if ablative treatment is contemplated.
    - Endocervical sampling is not indicated in pregnancy.
- Endometrial sampling is indicated in women with atypical endometrial cells and in all women aged 35 years or older who have AGC cytology results, as well as in women younger than 35 years with abnormal bleeding, morbid obesity, oligomenorrhea, or clinical results suggesting endometrial cancer.

- Women with HSIL cytology results and negative or unsatisfactory colposcopy results should undergo excision unless they are pregnant or adolescent.
- Women with AGC favor neoplasia or AIS cytology results and negative or unsatisfactory colposcopy results should undergo excision unless they are pregnant. A colposcopic examination negative for abnormalities after two AGC not otherwise specified (NOS) cytology results is also an indication for excision in the absence of pregnancy.
- Pregnant women with CIN 2 or CIN 3 may undergo follow-up with colposcopy during each trimester and should be reevaluated with cytology and colposcopy examinations at 6-12 weeks postpartum or thereafter. Treatment of CIN 2 and CIN 3 in pregnancy is not indicated.
- Women with CIN 2 or CIN 3 should be treated (in the absence of pregnancy) with excision or ablation. Management of CIN 2 in adolescents may be individualized.
- Women treated for CIN 2 or CIN 3 with a positive margin on excision may be followed by repeat cytology testing, including endocervical sampling every 6 months for 2 years or HPV DNA testing at 6 months; if these test results are negative, annual screening may be reestablished.
- Women with a cervical biopsy diagnosis of AIS should undergo excision to exclude invasive cancer. Cold-knife conization is recommended to preserve specimen orientation and permit optimal interpretation of histology and margin status.
- After treatment of CIN 2 or CIN 3, women may be monitored with cytology screening three to four times at 6-month intervals or undergo a single HPV test at 6 months before returning to annual follow-up.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Colposcopic examination during pregnancy should have as its primary goal the exclusion of invasive cancer. Excisions in pregnant women should be considered only if a lesion detected at colposcopy is suggestive of invasive cancer.
- Cervical cytology screening lacking endocervical cells may be repeated in 1 year when testing was performed for routine screening. Cytology screening performed for a specific indication (i.e., AGC follow-up or posttreatment follow-up after LEEP with a positive margin) may need to be repeated.
- Adolescents with ASC who are HPV positive or with LSIL results may be monitored with repeat cytology tests at 6 and 12 months or a single HPV test at 12 months, with colposcopy for a cytology result of ASC or higher-grade abnormality or a positive HPV test result.
- After treatment of AIS, when future fertility is desired and cervical conization margins are clear, conservative follow-up may be undertaken with cytology and endocervical sampling every 6 months.
- Women should not be treated with ablative therapy unless endocervical sampling test results are negative for abnormalities and the lesion seen and histologically evaluated explains the cytologic finding.
- In the absence of other indications for hysterectomy, excisional or ablative therapy for CIN 2 or CIN 3 is preferred.

Definitions:

Grades of Evidence

I: Evidence obtained from at least one properly designed randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Levels of Recommendations

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate screening and management of abnormal cervical cytology and histology

POTENTIAL HARMS

- Cervical cytology screening techniques are fraught with the potential for unnecessary visits, procedures, and patient anxiety. Conversely, the value of accurate screening results can be reduced by loss to follow-up or undertreatment of significant lesions that may progress to invasive cancer.
- Rates of cervical stenosis were comparable among ablative modalities in a randomized trial.
- In patients with cervical intraepithelial neoplasia (CIN), excision offers the advantage of a specimen for histologic examination and the disadvantage of increased surgical complications, primarily bleeding.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Combined testing (uterine cervical cytology and human papillomavirus DNA) is contraindicated in women who are immunosuppressed or who have had a total hysterectomy.
- Ablation should not be performed in patients with dysplasia on endocervical curettage.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Sep

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

- Abnormal Pap test results. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2004.

Electronic copies: Available from the American College of Obstetricians and Gynecologists (ACOG) Web site.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

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NGC STATUS

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